K103370

APR - 5 2011

RT200 Summary of Safety and Effectiveness

(1) Submitter's name, address, telephone number, a contact person, and the date the summary was prepared:

Andrew Barriskill
Restorative Therapies Inc
907 South Lakewood Ave
Baltimore, MD 21224

Phone: 800 609-9166

Prepared on March 5, 2010.

(2) Name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name:

Proprietary name: RT200 (FES elliptical ergometer)
Common name: Powered Muscle Stimulator
Classification name: External Functional Neuromuscular Stimulator

(3) Identification of the legally marketed device to which the submitter claims equivalence:

RESTORATIVE THERAPIES, INC. product: "RT300", K090750, a class 2 device

THERAPEUTIC ALLIANCES, INC. product: "ERGYS", K841112, a class 2 device. Relates to seat only.

(4) A description of the device that is the subject of the premarket notification submission.

The RT200 is a Functional Electrical Stimulation (FES) recumbent elliptical ergometer which is composed of:

1 a motorized elliptical ergometer (RTI part number SA110444)
2 an FES controller with built in 6 channel stimulator (RTI part number SA109413)
3 up to 5 additional wireless single channel stimulators (RTI part number FA106897)
4 a stimulation cable which connects the controller / stimulator to cutaneous electrodes
5 cutaneous electrodes (up to 22 electrodes for up to 11 stimulation channels)
6 an interface to a remote database for the storage and retrieval of therapy settings and the storage of therapy session logs

7 an interface to a pulse oximeter for the display and recording of pulse and SpO2 levels and provision of alarming based on the data
8 a stimwear garment incorporating electrodes for lower extremity cycling in population ages 12 and above (RTI part number FA105486)

This system allows a person with impaired upper or lower extremity movement to undertake recumbent elliptical ergometry both actively (utilizing FES evoked upper or lower extremity muscle contractions) and passively (utilizing power developed by the ergometer's motor).

(5) Statement of the intended use of the device:
The RT200 is intended for general rehabilitation for:
1. Relaxation of muscle spasms
2. Prevention or retardation of disuse atrophy
3. Increasing local blood circulation
4. Maintaining or increasing range of motion

The RT200 is intended for use with a surface electrical stimulation garment for population ages 12 and above.

The RT200 is for prescription use only.

(6) Technological Characteristics
The function of the RT200 is the same as the predicate devices however there are certain technological similarities and differences as described below:

Technology	RT200	RT300 predicate: K090750
Ergometer	Recumbent elliptical ergometer	Cycle ergometer
Power source (energy used)	Mains power and rechargeable battery for RT50 stimulators	Mains power and rechargeable battery for RT50 stimulators
Controller	Based on Pocket PC running custom software.	Based on Pocket PC running custom software.
Stimulator (energy delivered)	Built in AC mains powered 0-140mA 6 channel charge balanced stimulator.	Built in AC mains powered 0-140mA 6 channel charge balanced stimulator.
Additional stimulation channels	Up to 5 additional wireless battery powered stimulation channels delivering 0-140mA charge balanced stimulation.	Up to 5 additional wireless battery powered stimulation channels delivering 0-140mA charge balanced stimulation.
Stand alone stimulation mode	Wireless battery powered stimulation channels may be used in stand alone mode with out the cycle ergometer.	Wireless battery powered stimulation channels may be used in stand alone mode with out the cycle ergometer.
Stimwear garment	Stimwear garment incorporating electrodes	Stimwear garment incorporating electrodes

Technology	RT200	RT300 predicate: K090750
	available for lower extremity cycling, ages 12 and above.	available for lower extremity cycling, ages 12 and above.
Muscles available for stimulation	Quadriceps, hamstrings, gluteals, gastroc, anterior tibialis, shoulder, biceps, triceps, anterior, posterior and middle deltoid, wrist, grasp, abdominals, erector spinae.	Quadriceps, hamstrings, gluteals, gastroc, anterior tibialis, shoulder, biceps, triceps, anterior, posterior and middle deltoid, wrist, grasp, abdominals, erector spinae.
Flywheel	Uses leg / arm crank motor to create flywheel effect with reduced weight and space.	Uses leg / arm crank motor to create flywheel effect with reduced weight and space.
Seating	Utilizes built in seat as per K841112.	Allows user to remain in their own seating, e.g wheelchair eliminating the need for transfer.
Passive cycling	Utilizes motor to provide assistance during passive cycling.	Utilizes motor to provide assistance during passive cycling.
Database interface	Utilizes database interface for storage and retrieval of patient therapy settings and storage of session logs.	Utilizes database interface for storage and retrieval of patient therapy settings and storage of session logs.
Motorized arm crank	Allows active / passive arm cycling with FES. Arm crank is mechanically linked to the leg crank for simultaneous use.	Allows active / passive arm cycling with FES
Pulse oximeter interface	Utilize pulse and SpO2 data for display, recording and alarming	Utilize pulse and SpO2 data for display, recording and alarming
Bilateral or Unilateral stimulation	Uses bilateral or unilateral stimulation cables.	Uses bilateral or unilateral stimulation cables.

Table 1 Device technology comparison

(b) Performance data

Non clinical testing to determine equivalence has been primarily composed of the following tests:

Test or procedure	Description
Review of user documentation for predicate device	Ensure that equivalent functionality is specified and implemented in the new device.
Review of 510(k) submission for predicate device	Confirm technical specifications for completion of predicate details in

Test or procedure	Description
	comparison tables
Output characteristic measurement of new device	Confirm technical specifications for completion of new device details in comparison tables
Conduct of system testing	Conduct system testing to verify performance to specification.

Clinical Test	Description
Testing the RT200 recumbent elliptical ergometer and simultaneous upper and lower extremity stimulation.	The RT200 with 5 additional RT50 stimulation channels was validated with seven SCI individuals.

RTI concludes that:

The RT200 has the same intended use as the RT300 predicate device.

The RT200 has the same output characteristics as the predicate device. The RT200 utilizes the same control system as the predicate device including controller, motor controller and drive assembly. The different technological characteristics do not raise new questions of safety and effectiveness.

In conclusion, RTI's clinical and non-clinical testing has demonstrated that the RT200 is as safe and effective as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Restorative Therapies Inc
% Mr. Andrew Barriskill
907 S. Lakewood St
Baltimore, MD 21224

APR - 5 2011

Re: K103370
Trade Name: RT200 (FES recumbent elliptical ergometer)
Regulation Number: 21 CFR 882.5810
Regulation Name: External functional neuromuscular stimulator
Regulatory Class: Class II
Product Code: GZI
Dated: March 8, 2011
Received: March 9, 2011

Dear Mr. Barriskill:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include.requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K103370

Device Name: RT200 functional electrical stimulation elliptical ergometer

Indications for use:

The RT200 is intended for general rehabilitation for:
1. Relaxation of muscle spasms
2. Prevention or retardation of disuse atrophy
3. Increasing local blood circulation
4. Maintaining or increasing range of motion

The RT200 is intended for use with a surface electrical stimulation garment for population ages 12 and above.

Prescription Use X
(Part 21 CFR 801 Subpart D)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K103370